REMARKS

Claims 27, 29, 30, 32, 35, 36, and 38 have been previously withdrawn as directed in whole or in part to a non-elected species, without prejudice to applicant's rights to pursue these claims in another application. Claim 1 has been amended and claim 39 has been added. Support for new claim 39 may be found throughout the specification, specifically on pages 3-6. Therefore, no new matter has been introduced by new claim 39. Accordingly, claims 1, 2, 21-26, 28, 34, 37, and 39 are now pending in the present application.

Rejection of claims under 35 USC §112, second paragraph

The Examiner rejects claims 1, 2, 21, 22, 23-26, 28, 31, 34 and 37 under 35 U.S.C. §112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner maintains that certain phrases in these claims need clarification to define the invention.

The Examiner alleges that claim 1 is vague and indefinite because it is unclear what the term "interferes" means in the phrase, "interferes with at least one of the following interactions: a CLA and E-selectin interaction...." Applicant maintains

that it is clear from page 43, lines 10-17 of the specification that the interference of the stated interactions results in an inhibition of T cell rolling. On page 43, lines 1-4, the specification states, "...one need not immunosuppress or eliminate T cells, but rather one can provide an immunostimulator, as illustrated by the blastogenic assay reported in Tables 11, 12, 13 and 14." Therefore, in contrast to the Examiner's interpretation, interference with these interactions does not necessarily "encompass an inhibition" but may encompass immunostimulation of T cells. Applicant therefore maintains that the specification clearly defines the term "interfere."

However, to expedite prosecution, Applicant has amended claim 1 to specify that a portion of the compound is immunogenic. This amendment provides clarification that claim 1, as well as independent claims 2, 21, 22, 23-26, 28, 31, 34 and 37, are directed toward interference of the stated interactions using immunogenic means to inhibit of T cell rolling. New claim 39 specifically claims an immunotherapeutic agent comprising an antigen derived from isolated cells of amastigotes from at least one species of the *Leishmania* genus, and therefore is definite, as are amended claims 2, 21, 22, 23-26, 28, 31, 34 and 37, under 35 U.S.C. §112, second paragraph.

The Examiner also states that claims 21, 22, 23-26, 28, 31, 34 and 37 are vague and confusing because it is allegedly unclear whether the claimed methods intend to use isolated protein and/or mixtures of three isolated proteins or if the

agent is a purified protein extract as claimed in parent application 09/809,003, now U.S. Patent No. 6,673,351. According to the Examiner, a purified protein extract can continually change depending on the method used to isolate it from the killed amastigote cells, and therefore the extract should be defined as recited in claim 1 of U.S. Patent No. 6,673,351.

Applicant reiterates that U.S. Patent No. 6,673,351 is directed to immunotherapeutic agents that abate psoriasis, whereas the present continuation-in-part application is directed to methods of inhibiting T-cell rolling using a compound that interferes with a mechanism of action crucial to T-cell rolling. The present application provides additional information on pages 41-45 regarding the association between this mechanism and psoriasis or related maladies such as rheumatoid arthritis.

Since the present application is directed to methods of using any compounds that inhibit T-cell rolling, not to the specific compounds themselves, these compounds are adequately described as any "compound that interferes with at least one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VCAM interaction." Claim 21 describes these compounds in more detail, providing key characteristics such as their derivation from *Leishmania*, and their molecular weights.

The Examiner recommends that the claims should be defined as recited in claim 1 of U.S. Patent No. 6,673,351. Similar to claim 21 of the subject application, claim 1 of U.S. Patent No. 6,673,351 defines an agent of the invention as a "particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus...." Therefore, as with the subject application, claim 1 of parent US Patent No. 6,673,351 is also not limited to a specific compound.

As the Examiner states, the claims are not to be read in a vacuum. Section 2111.01, Plain Meaning, of the MPEP states that "[C]laims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their 'broadest reasonable interpretation'." 710 F.2d at 802, 218 USPQ at 292 (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). Accordingly, Applicant maintains that claim 21 and the claims dependent thereon adequately define the agent to be used in the claimed methods.

In view of the above arguments and amendments, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the pending claims under 35 U.S.C. §112, second paragraph.

Rejection of claims under 35 U.S.C. §112, first paragraph

The Examiner also maintains the rejection of claims 1, 2, 21, 22, 23-26, 28, 31, 34 and 37 under 35 U.S.C. 112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains to make and/or use the invention. Specifically, the Examiner maintains that the specification does not provide enablement for a method for selectively inhibiting T-cell rolling in a human susceptible to symptoms of psoriasis using **any** compound that interferes with at least one of the interactions listed (CLA and E-selectin, LFA-1/ICAM interaction or a VLA/VACM interaction), and that it would take undue experimentation to make and/or use the invention as claimed.

Applicant maintains that the specification enables a person skilled in the art to make or use the invention claimed in the present application. It is well established law that a specification need not contain a working example of every embodiment of the invention if the invention is disclosed in such a manner that one skilled in the art would be able to practice the invention. In contrast to the Examiner's allegation that the specification fails to demonstrate that any one immunotherapeutic agent in the specification specifically interfered with at least one of the interactions: CLA and E-selectin, LFA-1/ICAM or VLA/VCAM

interaction, Examples 14 and 15 of the present application demonstrate that the claimed agent induces a TH1 response, not humoral immunity or a TH2 response. The assays shown in Tables 11, 12, 13, and 14 indicate that the polypeptides of the invention inhibit lymphoid cell traffic from the blood to the skin, and from the blood to the synovial membrane. Since the specification also shows that interference with CLA-E selectin, LFA-1/ICAM and VLA/VCAM interactions is the mechanism by which such lymphoid cell traffic is inhibited, a person of ordinary skill in the art would be able to practice the invention without undue experimentation.

Furthermore, to expedite prosecution, Applicant has amended claim 1 to additionally define the compound as being at least partly immunogenic. Example 1 of the specification provides detailed instructions on preparation of an immunogen of the invention, thereby providing enablement for claim 1 and its dependent claims.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph.

Rejection of claims under 35 U.S.C. §102(a)

The Examiner also once again rejected claims 1 and 2 under 35 U.S.C. 102(a) as allegedly anticipated by Pariser, David M., *Managed Care*, December 2003, pp. 50-56 ("Pariser"). The Examiner maintains that the claimed subject matter, i.e., inhibiting T-cell rolling by inhibiting the listed interactions, is new matter presented as part of this continuation-in-part application, and therefore is not entitled to the priority date of the parent or grandparent applications.

Pariser does not teach each and every aspect of the claimed invention. Although Pariser describes LFA-1/ICAM interactions, this reference does not describe agents that interfere with CLA-E selectin or VLA/VCAM interactions as claimed in claim 1 of the present invention. Therefore, Pariser cannot anticipate the present application under 35 U.S.C. 102(a), since it does not teach each and every aspect of the pending claims.

The Examiner states that Applicant's argument that the subject invention is drawn to the use of agents that may act through a mechanism of immunostimulation while Pariser teaches the use of compounds that act as immunosuppressants, is not commensurate in scope with the claims. Applicant maintains that the compounds of the subject invention are derived from immunogens, i.e., antigens, not monoclonal antibodies such as efalizumab. On

page 42, line 25 to page 43, lines 1-4, the specification states that to treat any malady that "arises from the activity of lymphocytic infiltrate one need not immunosuppress or eliminate T cells, but rather one can provide an immunostimulator, as illustrated in the blastogenic assay reported in Tables 11, 12, 13 and 14..." Pariser teaches away from the present invention by teaching one to use agents such as monoclonal antibodies to bind to various antigens associated with T-cells or T-cell activation to immunosuppress the system, rather than agents to stimulate the system. Pariser does not disclose compounds that inhibit T cell rolling as claimed in the subject application. The present invention thereby provides a novel, innovative approach using immunostimulatory agents to treat psoriasis and related conditions.

To expedite prosecution, however, Applicant has amended claim 1 to specifically state that the compound is at least partly immunogenic, thus overcoming the rejection as anticipated by Pariser.

In view of the above arguments and amendments, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 1 and 2 under 35 U.S.C. §102(a).

Conclusion

Applicant believes the pending claims have been placed in condition for allowance by this amendment, and earnestly solicits early and favorable action by the Examiner. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-6170. The undersigned also may be contacted via e-mail at lweiss@lowenstein.com.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,

Lowenstein Sandler PC

By:

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